NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES, LTD. and TEVA PHARMACEUTICALS USA, INC. Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC. Defendants.	:	Civ. No. 07-2894 (GEB) (JJH) **MEMORANDUM OPINION**

BROWN, Chief Judge

This matter comes before the court upon the motion of defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") for partial summary judgment against plaintiffs Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva") that claims 1 and 2 of U.S. Patent No. 7,126,008 are invalid as anticipated by prior art. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 2201, 2202, 1331 and 1338(a). The Court has considered the parties' submissions and decided the matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, this Court will deny DRL's motion for partial summary judgment.

I. BACKGROUND

This patent infringement dispute concerns patents owned by Teva relating to carvedilol, the active pharmaceutical ingredient ("API") in COREG®, a product sold by GlaxoSmithKline

for the treatment of congestive heart failure. (Compl. ¶ 8, 18.)

On June 21, 2007, Teva filed its Complaint against DRL alleging that DRL intends to make tablets containing a carvedilol API that infringes on "one or more claims" in the Teva patents. (Compl. ¶¶ 22-28, 44-45.) Teva claims that upon final approval from the FDA of an Abbreviated New Drug Application ("ANDA") for carvedilol, DRL plans to make the tablets containing the infringing API. Teva also asserts that DRL has filed a Drug Master File with the FDA that indicates that DRL plans and intends to import, manufacture, use, sell or offer for sale to other ANDA holders a carvedilol API that will infringe on Teva's patents. (Compl. ¶¶ 29-37.) Teva seeks a judgment declaring that its patents are valid and enforceable and that DRL will willfully infringe or contribute or induce the infringement of the patents. (Compl. at 10-11.) In addition to attorney's fees, costs and expenses, Teva also seeks an injunction barring DRL from infringing or inducing infringement. (Id.)

On August 31, 2007, DRL filed its Answer, in which DRL counterclaims for a declaration that "each and every claim of the asserted patents is invalid" and that "DRL has not infringed any of the claims of any of the asserted patents." (Answer and Counterclaim at 9-10.)

The patent at issue in this partial summary judgment motion is U.S. Patent No. 7,126,008 ("the '008 patent"). The '008 patent discloses a process for preparing carvedilol. (Teva's L.R. 56.1 Statement ¶ 8; DRL's L.R. 56.1 ¶ 8.) Claims 1 and 2 of the '008 patent, the only claims at issue in this motion, discuss a process of preparing carvedilol by reacting an "epoxide" known as "formula II" with an "amine" known as "formula III" where the amine is at "molar excess" over the epoxide. Id. Specifically, claim 1 of the '008 patent states as follows:

1. A process for preparing carvedilol comprising a step of reacting a compound of

> formula II, 4-(oxiran-2-ylmethoxy)-9H-carbazole . . . with a compound of formula III, 2-(2-methoxyphenoxy)ethlamine . . . wherein the compound of formula III is in a molar excess over the compound of formula II.

Ex. 1 to the Declaration of Michael H. Imbacuan ("Imbacuan Decl.") (graphics omitted). Claim 2 of the '008 patent states as follows:

> 2. The process of claim 1, wherein the compound of formula III and the compound of formula II are at a molar ratio from about 1.5:1 to about 100:1.

Id.

On October 12, 2007, DRL filed the present motion for partial summary judgment that claims 1 and 2 of the '008 patent are invalid under 35 U.S.C. § 102(b) for anticipation.

II. DISCUSSION

A. Standard of Review for Motions for Summary Judgment

In deciding a motion for summary judgment, a court should grant the motion if "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). See also Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Orson, Inc. v. Miramax Film Corp., 79 F.3d 1358, 1366 (3d Cir. 1996). The threshold inquiry is whether "there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). In deciding whether triable issues of fact exist, the court must view the underlying facts and draw all reasonable inferences in favor of the non-moving party. See Hancock Indus. v. Schaeffer, 811 F.2d 225, 231 (3d Cir. 1987). In arguing against a motion for summary judgment, "an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response . . . must

set forth specific facts showing that there is a genuine issue for trial." FED. R. CIV. P. 56(e).

B. Anticipation of a Patent

The law governing the anticipation of a patent is well-settled. Under 35 U.S.C. § 102, a person is not entitled to a patent if the invention was "described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). A finding of invalidity based on anticipation under 35 U.S.C. § 102 requires a determination that "each and every limitation is found either expressly or inherently in a single prior art reference." PIN/NIP, Inc. v. Platte Chem. Co., 304 F.3d 1235, 1243 (Fed. Cir. 2002) (quoting Celeritas Techs., Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1360 (Fed. Cir. 1998)). Because a patent that was issued by the Patent and Trademark Office enjoys a presumption of validity, the evidence supporting such a finding must be clear and convincing. Id. "[W]hen the prior art before the court is the same as that before the PTO, the burden on the party asserting invalidity is more difficult to meet." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 447 (Fed. Cir. 1986). Whether a patent is anticipated by a prior art reference is a question of fact. Schumer v. Lab. Computer Sys., 308 F.3d 1304, 1315 (Fed. Cir. 2002).

C. Claim 1 of the '008 Patent

1. Parties' Arguments

DRL argues that claim 1 should be dismissed because it is anticipated by U.S. Patent No. 4,503,067 ("the Wiedermann patent") and U.S. Patent No. 5,071,868 ("the Leinert Patent"). In its opposition brief, Teva states that it "will not assert Claim 1 of the '008 Patent against DRL in this or any future litigation. Accordingly, it is not an issue here and DRL has no reasonable

apprehension of being sued on Claim 1 in the future. Therefore, Claim 1's validity is moot and need not be decided by this Court."[1] (Opp. Br. at 7.) Teva concludes that there is no case or controversy here with respect to claim 1 and therefore summary judgment on invalidity as to claim 1 should not be granted.

DRL argues that Teva "cannot preserve an invalid patent by unilaterally declaring in its opposition brief that the issue is moot," because DRL has filed a "counterclaim seeking a declaratory judgment that claims 1 and 2 of the '008 patent are invalid. " (DRL Reply Br. at 7.) DRL claims that there is "necessarily" a case or controversy because Teva "actually charged DRL with infringement of the '008 patent." Id. at 8. DRL opines that a failure to resolve the validity of claim 1 would "multiply the opportunities" for Teva to sue the customers that DRL supplies with carvedilol. (Id. at 8.) Finally, DRL apparently argues that Federal Rule of Civil Procedure 41(a) prevents Teva from declaring the validity issue moot "by fiat." (Id. at 10.)[2]

2. Declaratory Judgment Act

The Declaratory Judgment Act provides that, "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations

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[1]As DRL properly notes, the "reasonable apprehension" standard for declaratory judgment jurisdiction referenced by Teva has been rejected by the Supreme Court. Sandisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1380 (Fed. Cir. 2007) (acknowledging that Supreme Court rejected the reasonable apprehension of suit test).

[2]The Court will not consider Teva's proposed sur-reply to the extent that it addresses claim 1 of the '008 patent. Pursuant to Local Rule 7.1(d)(6), sur-replies are not permitted without prior permission from the Court. By letter dated November 6, 2007, Teva sought permission to file the proposed sur-reply due to "newly minted arguments" regarding Claim 2 that were purportedly made in DRL's reply brief. The Court has not been presented with any reason to allow a sur-reply as to claim 1 of the '008 patent. Therefore the Court will disregard the sur-reply to the extent it addresses this claim.

of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). "A party seeking to base jurisdiction on the Declaratory Judgment Act bears the burden of proving that the facts alleged, 'under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" Benitec Australia, Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1343 (Fed. Cir. 2007) (citations omitted). "The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." Id. at 1344 (citing Steffel v. Thompson, 415 U.S. 452, 459 n.10 (1974)). "[O]nce that burden has been met, *absent further information*, that jurisdiction continues. The burden of bringing forth such further information may logically rest with the party challenging jurisdiction, but the actual burden of proof remains with the party seeking to invoke jurisdiction." Id. at 1344-45 (internal citations omitted) (emphasis in original). A case or controversy "must be extant at all stages of review, not merely at the time the complaint [was] filed." Id. at 1345 (quoting Steffel, 415 U.S. at 459 n.10). In patent cases, the existence of a "case or controversey must be evaluated on a claim-by-claim basis." Jervis B. Webb Co. v. Southern Systems, Inc., 742 F.2d 1388, 1399 (Fed. Cir. 1984).

3. Court's Analysis

The Court will deny DRL's summary judgment motion to the extent it concerns claim 1 of the '008 patent because there is no case or controversy as to that claim. At the time DRL filed its declaratory judgment action, there was a case or controversy regarding claim 1 of the '008 patent, because infringement of the '008 patent had been alleged in Teva's complaint. See

Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 96 (1993) ("[i]f . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction"). But the issue is whether in light of Teva's statement in its Opposition Brief that it "will not assert Claim 1 of the '008 Patent against DRL in this or any future litigation," there is, at this time, a case or controversy as to Claim 1 of the '008 Patent. The Court concludes that there is not.

In Benitec Australia, Ltd. v. Nucleonics, Inc., 495 F.3d 1340 (Fed. Cir. 2007), Benitec sued Nucleonics for patent infringement. Nucleonics asserted declaratory relief counterclaims of invalidity and unenforceability. Benitec moved to dismiss its complaint without prejudice under Federal Rule of Civil Procedure 41(a)(2). The district court granted Benitec's motion to dismiss its complaint without prejudice and dismissed Nucleonics counterclaims for lack of jurisdiction. Nucleonics appealed the dismissal of its declaratory judgment counterclaims. In its brief to the Federal Circuit, Benitec stated that it "covenants and promises not to sue Nuclonics for patent infringement arising from activities and/or products occurring on or before the date dismissal was entered." The Federal Circuit ruled that although there was a case or controversy at the time the counterclaims were filed, there was no longer a case or controversy because Benitec made its covenant and sought dismissal of its infringement claims.

The present case is similar to Benitec. Teva stated in its brief that it "will not assert Claim 1 of the '008 Patent against DRL in this or any future litigation." Although, Teva has not moved to dismiss its complaint, the Court does not find this difference controlling. The case or controversy requirement must be evaluated claim by claim, Jervis B. Webb Co., 742 F.2d at 1399, and Teva has conceded that it is not pursuing an infringement claim as to claim 1 of the

'008 patent. DRL contends that does not contend that Teva cannot deprive the court of declaratory judgment jurisdiction through a unilateral declaration in its brief. In light of Benitec, the Court cannot agree.[3]

The Court also rejects DRL's argument that Teva's suit against Ranbaxy, a customer of DRL, is sufficient grounds for declaratory judgment jurisdiction. DRL has cited no authority to support this position and does not explain how Teva's suit against Ranbaxy, a non-party, constitutes a "substantial controversy, between [Teva and DRL], of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." See Benitec, 495 F.3d at 1343 (citations omitted)

Thus the Court concludes that there is not a present case or controversy between Teva and DRL, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment as to Claim 1 of the '008 patent.

Finally, the Court rejects DRL's argument that Teva's actions are somehow inappropriate under Rule 41(a). Rule 41(a) concerns when and how a plaintiff may dismiss an entire action. See New West Urban Renewal Co. v. Viacom, Inc., 230 F.Supp.2d 568, 571 (D.N.J. 2002) (Rule 41(a) "applies to dismissals of entire actions and not to individual claims"). Here, Teva is not seeking to dismiss the entire action.[4]

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[3]DRL encourages the Court to follow SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372 (Fed. Cir. 2007), but the Benitec court distinguished SanDisk by noting that the patent holder in Sandisk "only stated that it did not *intend* to sue SanDisk; it did not say it *would not* sue SanDisk in the future for its alleged infringment." Benitec, 495 F.3d at 1347 (emphasis in original). For the same reason, SanDisk is distinguishable from the present case.

[4]DRL's citation to Minnesota Mining & Mfg. Co. v. Barr Labs., Inc., 289 F.3d 775 (Fed. Cir. 2002) is not helpful. Unlike the court in that case, this Court does not conclude that Teva's statements concerning Claim 1 of the '008 patent are made merely to avoid an invalidity

Therefore DRL's summary judgment motion is denied to the extent it concerns Claim 1 of the '008 patent.

D. Claim 2 of the '008 Patent

1. Parties' Arguments

DRL argues that Claim 2 of the '008 patent is invalid because it was anticipated by the Leinert patent, which was issued on December 10,1991. In example 7 of the Leinert patent, an R-isomer of the epoxide was reacted with the amine to produce the R-isomer of carvedilol. (Teva L.R. 56.1 Statement ¶ 35; DRL L.R. 56.1 ¶ 35.) The calculated molar ratio of amine to epoxide in example 7 is 1.97:1. (Teva L.R. 56.1 Statement ¶ 36; DRL L.R. 56.1 ¶ 36.) In example 8 of the Leinert patent, an S-isomer of the epoxide was reacted with the amine to produce the S-isomer of carvedilol. (Teva L.R. 56.1 Statement ¶ 37; DRL L.R. 56.1 ¶ 37.) The calculated molar ratio of amine to epoxide in example 8 is 1.99:1. Thus, DRL contends that Claim 2 is anticipated by the Leinert Patent, which discloses molar ratios within the 1.5:1 to 100:1 range of Claim 2. DRL also contends that the '008 patent is anticipated by the Leinert patent because "a genus is anticipated by the prior disclosure of a species within the genus."

Teva responds that the Leinert patent does not contain "at least two critical elements" of Claim 2. (Pl.'s Opp. Br. at 11.) First, according to Teva, "[t]he Leinert reference is not directed to a process of preparing carvedilol, but is instead directed to a process of preparing R- and S-

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judgment that would be adverse to its interest. Teva simply contends that it need not identify in its Complaint that the particular claims of the patents-in-suit that it believes DRL will infringe. See Opp. Br. at 8 ("Teva was not required to identify the claims it would assert at the outset of this litigation"); Ex. 8 to the Declaration of Michael H. Imbacuan (indicating that Teva is asserting infringement of one or more of the claims of the '008 patent).

enantiomers of carvedilol." (Id.)[5] Second, in a related point, Teva argues that the "'008 Patent uses a racemic epoxide[, but t]he Leinert reference . . . does not disclose a racemic epoxide." (Id.)[6] Teva concludes that the "absence of these elements is sufficient to defeat anticipation." (Id.) In the alternative, Teva argues that if the Court finds it premature to rule on the anticipation issue, the Court should "defer the Motion until claim construction is complete." (Id. at 11-12.)

DRL counters that "there is no racemic limitation [on the epoxide used] in claim 2." (Def.'s Br. at 4.) DRL points to the "chemical formula" for the '008 Patent and states that it "describes the R- and S- stereoisomers and the racemate." (Id. at 5.) Therefore, according to DRL, "claim 2 is not limited to reactions involving a 'racemic epoxide.'" (Id.) Similarly, DRL argues that claim 2 of the '008 Patent includes both the stereoisomers and the racemate of carvedilol. Specifically, DRL cites language from the '008 patent that states that carvedilol "can exist either as individual stereoisomers or in racemic form." (Def.'s Reply Br. at 5). DRL asserts that "[e]xamples 7 and 8 of Leinert disclose" a process for preparing carvedilol and the fact that "the specific examples cited in Leinert yield stereoisomers of carvedilol does not change this fact." (Id.) DRL also argues that Teva's argument is "belied by its failure to make this distinction when it prosecuted claims identical to claims 1 and 2 in this motion in the parent to the '008 patent." (Id. at 6.) DRL claims that Teva "never suggested that Leinert was

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[5]Molecules that have the same chemical formula, but have different spatial arrangements are referred to as stereoisomers. Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1372 (Fed. Cir. 2006). Enantiomers, also known as antipodes, are stereoisomers that are nonsuperimposable mirror images of each other, which differ in structure due to the "left- and right-handednessof their orientation." (Teva L.R. 56.1 Statement ¶ 41; DRL L.R. 56.1 ¶ 41.)

[6]Racemates, also known as racemic mixtures, are mixtures of equal amounts of enantiomers, such that the mixture is not oriented to the left or the right. (Teva L.R. 56.1 Statement ¶ 41; DRL L.R. 56.1 ¶ 41; Ex. F to the Declaration of Michael E. Patunas.)

distinguishable because it taught only stereoisomers of carvedilol." (Id.) DRL claims that Teva did not distinguish the Leinert claim as dealing only with stereoisomers because "Teva did not consider its invention to be limited to only racemic carvedilol." (Id.) Thus, according to DRL, this Court should not now accept the distinction between stereoisomers and racemic carvedilol as being significant. (Id.)

In its sur-reply, Teva states that "stereoisomers are different than the standard racemic form of a chemical compound." (Def.'s Sur-Reply at 1.)[7] Teva notes that the "Leinert references itself" states that "[t]he pharmaceutical effectiveness of the particular antipodes is, in comparison with the racemate, greatly different." (Id. at 2.) Teva claims that DRL tries "to create a supposed definition of the term 'carvedilol'" and merely offers "attorney argument in lieu of scientific evidence on the relationship between racemates and stereoisomers." (Id.) Teva downplays the portion of the '008 Patent stating that "[c]arvedilol . . . can exist either as individual stereoisomers or in racemic form" by arguing that this statement should not be taken to define the term absent a clear intention by the patentee. The lack of such a clear intention is, according to Teva, evidenced by the presence of the (±) symbol at the beginning of the chemical formula identified in the '008 patent specification as carvedilol. Teva asserts that this symbol "affirmatively designates the racemic form of carvedilol." According to Teva, "[t]o designate the stereoisomers, the patentee would have included an R- or S- prior to the chemical formula." Id. Teva also directs the Court to the sentence in the specification stating that "Racemic carvedilol is the active ingredient of COREG®, which is indicated for the treatment of congestive heart failure

[7]The Court will consider Teva's sur-reply to the extent it addresses the definition of carvedilol as used in Claim 1 of the '008 patent. This issue was not directly addressed in the moving brief.

and hypertension," which, according to Teva, indicates that the racemic form is the object of the invention. Teva concludes that DRL's assertions do not "overcome by clear and convincing evidence the strengthened presumption of validity." (Id. at 2.)

2. Court's Analysis

The Court concludes that DRL's motion is premature as to claim 2. As DRL recognizes, its argument as to claim 2 depends on whether claim 2 requires the use of a racemic epoxide to produce racemic carvedilol. (Def. Reply Br. at 4-6.) This determination requires the Court to construe the term "carvedilol" as used in claim 1. Claim construction is a matter of law, Markman v. Westview Instrs., Inc., 52 F.3d 967, 979 (Fed. Cir.1995) aff'd 517 U.S. 370 (1996), and it is "[t]he duty of the trial judge ... to determine the meaning of the claims at issue." Exxon Chem. Patents, Inc. v. Lubrizoil Corp., 64 F.3d 1553, 1555 (Fed. Cir.1995). "[I]t is essential to understand the claims before their breadth is limited for purposes of preserving validity." Nazomi Comms., Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368-69 (Fed. Cir. 2005). Although the parties do discuss how they wish the Court to construe the term "carvedilol," the issue was not raised in DRL's moving brief and both sides have not fully addressed the issue. For example, in its sur-reply, Teva highlights a section of the specification of the '008 patent that states that "[c]arvedilol, also known as ± 1-(9H-carbazol-4-yloxy)-3-[[2(2-methoxyphenoxy)ethyl]amino]-2-propanol, CAS Registry No. 72956-09-3) has the structure of formula I." According to a document submitted with the sur-reply, "[a] racemic mixture is often specified by prefixing the name of the compound with the symbol ± . . . ." Andrew Streitwieser, Jr. & Clayton H. Heathcock, Introduction to Organic Chemistry131 (2d Ed. 1981). Although DRL objected to the sur-reply by 4-page letter, DRL did not discuss the ± symbol, only stating

that "irrelevant statements from scientific texts . . . should be given little, if any, weight." The Court concludes that claim construction briefing, if not a hearing, is required before claim construction can be determined.

Additionally, the Court concludes that DRL's genus/species argument is not a proper basis for summary judgment at this time. Although neither party disputes that a racemate is a mixture of equal amounts of the enantiomers, DRL has not shown by clear and convincing evidence that the disclosure of a process for making carvedilol stereoisomers will anticipate a process for making the racemate. DRL merely insists upon the fact, without any supporting scientific evidence, let alone clear and convincing evidence. Indeed, DRL has not offered any expert testimony or other evidence regarding the similarities or differences between the processes required to produce stereoisomers and the racemate forms of carvedilol.[8] Therefore, summary judgment on these grounds is not appropriate.

Without claim construction, the Court cannot find by clear and convincing evidence that each and every limitation in the '008 patent is found in the Leinert patent. Therefore, the Court will deny DRL's summary judgment motion as to claim 2 of the '008 patent without prejudice to refile after a ruling on claim construction.

[8]Although DRL cites Aventis Pharma Deutschland GmbH v. Lupin Ltd., No. 2:05 CV 421, 2006 WL 2008962, at **36-37 (E.D. Va. July 17, 2006), a post-bench trial opinion, DRL concedes in its letter to the Court dated November 20, 2008 that the case is not direct authority for the proposition that stereoisomers anticipate the racemate.

III. CONCLUSION

For the foregoing reasons, DRL's Motion for Partial Summary Judgment is denied. An appropriate form of order is filed herewith.

Dated: March 4, 2008

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.